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10/623,316	07/17/2003	Robert W. Childers	DI-5766	3437

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BELL, BOYD & BOYD LLP
70 W. MADISON SUITE 3100
CHICAGO, IL 60602

EXAMINER	
CHAPMAN, GINGER T	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-26, drawn to a system for providing dialysis, classified in class 604, subclass 5.01.

Group II. Claims 27-34, drawn to a cassette, classified in class 210, subclass 646.

Group III. Claims 35-39, drawn to a dialysis therapy device, classified in class 604, subclasses 6.11, 6.13.

Group IV. ,Claims 40-56, drawn to methods for performing peritoneal dialysis, classified in class 604, subclass 29.

Group V. Claims 57-61, drawn to methods of performing peritoneal dialysis and hemodialysis, classified in class 210, subclass 645.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I & II and Groups I & III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination has separate utility such as a tubing set for an irrigation-pump fluid delivery system.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claims depending from or otherwise requiring all the limitations of the allowable

subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions Groups II & III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as a tubing set for an irrigation-pump fluid delivery device. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claims depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions Groups I & IV and Groups I & V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation, which result in different treatment effects.

Inventions Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation resulting in different treatment effects.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Robert Connors on 12 December 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "controller" must be shown or the feature canceled from the claims. No new matter should be entered.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "medical fluid regenerator" must be shown or the feature canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Language Interpretation

It is noted that the terminology "nanofilter" has not been specifically defined by Applicants and thus will be given their broadest customary interpretation, i.e. the dictionary definition, in light of the specification. Therefore, in light of the specification at [0196] that the nanofilter operates similar to the dialyzer and includes a membrane that rejects most electrolytes, i.e. allows most of the electrolytes to return to the solution bag, and filters most all of the urea and a small amount of sodium through the membrane; and the dictionary definition of "filter", i.e. "1 a : a porous article or mass (as of paper or sand) through which a gas or liquid is passed to

separate out matter in suspension; b : an apparatus containing a filter medium". The terminology "nanofilter" is being considered as an apparatus containing a membrane as the filter medium.

Claim Objections

Claim 16 is objected to because of the following informalities: line two recites, "...flow in opposite directions through the multiple patient." In view of the specification p. 6, ll. 8-11 and p. 14, ll. 18-29, examiner is considering this a typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 13, 15, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg (US 5,522,998).

With regard to claim 1, as seen in Figure 1, Polaschegg discloses a system for providing dialysis comprising: a patient fluid loop (20) including a first pump (22) and multiple patient lumens (c. 5, l. 20); a second fluid loop (40) including a second pump (52) and a medical fluid regenerator (12); a membrane device (14) in fluid contact with and separating the patient fluid loop (20) and the second fluid loop (40), the membrane device allowing at least one selected component of the fluid in the patient fluid loop to transfer to the second fluid loop; the second loop being closed except for the transfer of the selected component via the membrane device (fig. 1); and a controller (64) that operates the pumps to recirculate fluid in the patient loop (20) and the second loop (40).

With regard to claim 2, Polaschegg discloses a dialyzer (12).

With regard to claim 3, Polaschegg discloses a pressure gradient (c. 4, ll. 29) across the membrane device (14).

With regard to claim 4, Polaschegg discloses the patient loop is closed except for the transfer of the selected component via the membrane device (c. 1, l. 65).

With regard to claim 13, Polaschegg discloses blood circulated through the patient fluid loop (c. 5, l. 15-20).

With regard to claim 15, Polaschegg discloses a balance chamber (30) that balances flow within the second fluid loop (40).

With regard to claim 24, Polaschegg discloses an ultrafiltrate container (54) in fluid communication with second fluid loop (40).

With regard to claim 25, Polaschegg discloses a fluid concentrate container (42) in fluid communication with the second fluid loop (40).

Claims 5-7 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Burbank et al (US 2001/0041892 A1).

With regard to claim 5, Polaschegg discloses the invention substantially as claimed except for a nanofilter. Polaschegg, at c. 4, ll. 25-50 teaches the ability of a membrane to filter urine component substances, i.e. urea, through the membrane to remove the urine components thus disclosing a desire to filter urine components, i.e. urea, through a membrane filter. Burbank ('892), at [0002] discloses the desire and motivation to diffuse uremic toxins out of a patient's blood through a semipermeable membrane by utilizing the concentration gradient across the membrane. As seen in Figure 1, Burbank ('892) disclose a system for providing dialysis comprising patient fluid loop (12) and a second loop (70) and including a membrane device (50) including a nanofilter (52) which allows urea to pass from a patient fluid loop (12) to a second fluid loop (70) including a medical fluid regenerator (44). Therefore it would have been obvious to one having ordinary skill in the art to use the nanofilter of Burbank ('892) in the system of

Polaschegg to allow urea to pass since Burbank states at [0051] that such a membrane retains blood components for return to the patient while allowing passage of toxins and at [0058] that such a filter provides treatment of uremic toxin containing blood or peritoneal dialysate to provide cleansed blood for infusion to the patient.

With regard to claims 6 and 7, Burbank ('892) discloses the medical fluid regenerator (44) includes a uremic toxin sorbent [0052] and contains carbon (46).

With regard to claim 12, Burbank ('892) discloses peritoneal dialysis fluid is circulated through the patient fluid loop [0013].

With regard to claim 13, Burbank ('892) discloses at [0063] that blood (22) is circulated through the patient loop (12, 28) for return of cleared blood to back to the patient.

With regard to claim 14, Burbank ('892) discloses at least parts of the patient fluid loop (216) and the second fluid loop (192) are provided in a disposable device [0079].

Claims 16, 21-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Burbank et al (US 6,579,253 B1).

With regard to claim 16, Polaschegg discloses the invention substantially as claimed but does not expressly disclose the controller enables fluid flow in opposite directions through the multiple patient lumens. Polaschegg, at c. 7, ll. 1-20 teaches the ability of the controller to enable fluid to flow through the dialysis system thus disclosing a desire for such. Burbank ('253), at c. 10, ll. 37-38 expresses the desire to enable fluid to flow in opposite directions through the patient lumens to rinse back blood to the patient. As seen in Figures 1 and 11, Burbank ('253) teaches a system (fig. 1) for providing dialysis comprising a patient fluid loop

(62) and a second fluid loop (68) and controller (22) enabling fluid to flow in opposite directions through the patient lumens (c. 21, ll. 25-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the controller of Polaschegg enable fluid to flow in opposite as taught by Burbank ('253) since Burbank states at c. 21, ll. 35-38 that the benefit of operating the system in this mode is that it returns fluid to a patient in a bolus volume, e.g. during a hypotensive episode or during rinse back at the end of a treatment session.

With regard to claims 21, 22 and 23, Burbank ('253) discloses a fluid volume sensor (182) in at least one of the patient and second fluid loops (68); the sensors can be, *inter alia*, capacitance sensors (c. 23, ll. 35-40; c. 11, l. 48) that use a pump chamber (214) in fluid communication with the loop (68).

With regard to claim 26, Burbank ('253) discloses the controller operates the pump (144) continuously to pump fluid into and out of a patient (c. 7, ll. 7-8; c. 21, ll. 3-9).

Claims 8-11 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Savitz et al (US 4,229,299).

With regard to claims 8 and 10, Polaschegg discloses the invention substantially as claimed except for a gas separator and gas vent. Savitz et al, at c. 5, ll. 10-25 expresses the desire and motivation to prevent any gas from being returned with the blood to a patient's body. As seen in Figures 1-3, Savitz et al teach a system for providing dialysis comprising a patient fluid loop (C), a second fluid loop (A) and medical fluid regenerator (123), a membrane device (112), a controller (c. 4, l. 63), a gas separator (153) that removes gas from at least one of the

patient and second fluid loops and a gas vent (154) that vents gases. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Polaschegg including gas separator and vent as taught by Savitz since Savitz states at c. 5, ll. 22-24 that such a gas separator prevents any gas from being returned with the blood to the patient's body and at c. 13, ll. 15-30 that the vent serves as an outlet for gas desolubilized from the water and additionally functions as an overflow discharge means thereby providing a safer dialysis system.

With regard to claim 9, the combination of Polaschegg and Savitz disclose the invention substantially as claimed except for the gas separator (153) and medical fluid regenerator (123) provided in a single device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gas separator and medical fluid regenerator in a single device since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893).

With regard to claims 11 and 20, Savitz discloses a multi-analyte sensor (105) that monitors a concentration of electrolytes, e.g. ammonium, in the medical fluid (c. 6, ll. 40-55).

With regard to claim 18, Savitz discloses at least one of the patient fluid loop (C) and the second fluid loop (B) includes an in-line fluid heater (103,152).

With regard to claim 19, the combination of Polaschegg and Savitz discloses heaters (see claim 18, *supra*) but does not expressly disclose a radiant heater and a plate heater. Savitz, at c. 12, ll. 28-29 teaches that the heaters can be of any suitable conventional type of heater and at c. 6, ll. 5-35 that such heating is carried out for the purpose of maintaining the fluid at a proper

temperature to prevent undue heating or cooling of the blood and to prevent hemolysis. In view of the teachings of Savitz, it would have been obvious to one having ordinary skill in the art at the time the invention was made that the heaters disclosed by Savitz are fully capable of comprising radiant or plate heaters because Savitz states at c. 12, ll. 28-29 that any suitable conventional heater may be used, therefore these heaters are equivalent for the desired purpose of maintaining proper temperature; two equivalents are interchangeable for their desired function, express suggestion of substitution not needed to render such substitution obvious. *In re Siebentritt*, 54 CCPA 1083.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg in view of Geary et al (US 4,950,259).

With regard to claim 17, Polaschegg discloses the invention substantially as claimed but does not expressly disclose a dual lumen catheter. Polaschegg, at c. 5, ll. 15-20 expresses the desire to connect the dialysis system to a patient. Geary et al, at c. 1, ll. 45-68 expresses the desire for a catheter comprising more than a single lumen to increase the efficiency of peritoneal dialysis. As seen in Figures 1-3, Geary et al teach a dual lumen catheter (8) for use with a system for providing dialysis. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the connection of Polaschegg comprising a dual lumen catheter as taught by Geary since Geary states at c. 8, ll. 47-60 and c. 9, ll. 10-20 that the advantage of using such a dual lumen catheter is that it maintains a greater solute concentration and osmotic gradient over that of a single lumen catheter and permits continuous flushing thereby providing greater dialysis efficiency.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chevallet (US 5,366,630) discloses a system for providing hemodialysis wherein impurities in the blood are diffused through semipermeable membrane which irrigated by a flow of dialysis liquid free of the substances to be removed such that transfer is driven by the concentration differences across the membrane, and haemofiltration by ultrafiltration through a semipermeable membrane wherein transfer is driven by the pressure differences across the membrane (c. 1, ll. 30-60).

Krivitski et al (US 5,685,989) teaches that fluid volume sensors suitable for dialysis systems can comprise sound velocity sensors, electrical impedance sensors, optical sensors, thermal sensors, isotope sensors or the like because these sensors are equivalent for their desired function.

Burbank et al (US 2001/0037079 A1) discloses a dialysis system for clearing a patient's blood of uremic toxins [0029].

Burbank et al (US 2002/0147423 A1) discloses a continuous dialysis system for performing dialysis during overnight treatment regimes [0032].

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
12/21/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER